



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-16ET]**

**[Docket No. CDC-2015-0107]**

**Proposed Data Collection Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS)

**ACTION:** Notice with comment period

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project entitled "Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color." Seven U.S. health departments

will form, lead, and coordinate a collaborative with 37 community-based organizations (CBOs), clinics and other health providers, behavioral health and social health providers in their jurisdictions. The collaborative will report standardized program monitoring and evaluation (M&E) data to the health department and then the health department will report the same M&E data to CDC.

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0107 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a

proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

## Proposed Project

Comprehensive HIV Prevention and Care for Men Who Have Sex With Men of Color - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Approximately 50,000 people in the United States are newly infected with HIV each year. Gay, bisexual, and other men who have sex with men (MSM) remain the US population most heavily affected by HIV infection. Among MSM, those who are black and Hispanic comprise 58% of all new infections. To address the burden of HIV in this population, high impact HIV prevention approaches should be implemented by state, local, and territorial health departments to reduce new HIV infections among MSM of color, and to improve outcomes along the HIV continuum of care for MSM of color living with HIV.

Antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP) can be used for HIV prevention by MSM at substantial risk for HIV acquisition or by those with a possible HIV exposure in the past 72 hours post-exposure prophylaxis (nPEP). The daily use of co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada) for PrEP has

been proven to significantly reduce the risk of HIV acquisition among sexually active MSM. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published clinical practice guidelines for provision of PrEP. Given the high incidence of HIV among MSM of color, those who are sexually active are considered at risk for HIV acquisition and thus could benefit from prevention services such as routine and frequent HIV screening with lab-based 4th generation HIV tests, routine screening for STDs, assessment of PrEP eligibility, provision of PrEP (if at substantial risk for HIV acquisition), provision of nPEP (if a possible HIV exposure occurred in the past 72 hours), and/or other risk reduction interventions.

Among people living with HIV (PLWH), ARV treatment can suppress HIV viral load, which both improves health outcomes of individuals and reduces the risk of HIV transmission. Two studies, one that demonstrated the effectiveness of ARV treatment in preventing HIV transmission, and one that demonstrated improved health outcomes for individuals whose ARV treatment was initiated immediately, have led to increased public health focus on interventions and strategies designed to initiate ARV treatment, link, retain, and re-engage PLWH in HIV care, and to provide support for adherence to ARV medications.

The purpose of this project is to support state and local

health departments to develop and implement demonstration projects for provision of comprehensive HIV prevention and care services for MSM of color by creating a collaborative with CBOs, clinics and other health care providers, and behavioral health and social services providers in their jurisdiction. Behavioral health services include mental health and substance abuse treatment to enable MSM of color to utilize HIV prevention and care services; social services include services that promote access to housing, job counseling, and employment services to enable MSM of color to utilize HIV prevention and care services.

Comprehensive models of HIV prevention and care for MSM of color will be developed and implemented by a collaborative that is led by the jurisdiction's health department and includes the following: health care providers (e.g., federally qualified health centers (FQHCs), FQHC Look-Alikes, other clinics, or health care providers); HIV care providers (e.g., clinics funded through the Ryan White HIV/AIDS Program (RWHAP clinics), other HIV care clinics, or HIV care providers); behavioral health and social services providers (i.e., mental health and substance abuse services, housing programs, and job training or employment services); and community based organizations (CBOs). Principles of high impact prevention should guide the selection and implementation of activities and strategies to focus on MSM of color at substantial risk for HIV infection (i.e., eligible for

prevention with PrEP), and those living with HIV. MSM of color who are at risk for HIV acquisition (i.e., sexually active) but not eligible for or decline PrEP will be provided risk reduction interventions, partner services if diagnosed with an STD, re-testing for HIV and STDs in 3-6 months, and behavioral health and social services. The risk of HIV acquisition should be assessed at every encounter with an individual, and MSM of color at substantial risk of HIV acquisition should be offered PrEP when indicated by the risk assessment.

There are a total of 24 required HIV prevention and care services that must be provided by the health department collaborative for this project. This is to include thirteen HIV prevention services for MSM of color at substantial risk for HIV infection and eleven HIV care services for MSM of color living with HIV infection. The following are the thirteen HIV prevention services: 1. HIV testing services that use lab-based 4th generation HIV tests; 2. Assessment of indications for pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP); 3. Provision of PrEP and nPEP; 4. Adherence interventions for PrEP and nPEP; 5. Immediate linkage to care, ARV treatment, and partner services for those diagnosed with acute HIV infection; 6. Expedient linkage to care, ARV treatment, and partner services for those diagnosed with established HIV infection; 7. STD screening and treatment; 8.



Partner services for patients with STDs; 9. Behavioral risk reduction interventions; 10. Screening for behavioral health and social services' needs; 11. Linkage to behavioral health and social services; 12. Navigators to assist accessing HIV prevention and behavioral health and social services; 13. Navigators to assist enrollment in a health plan. The following are the eleven HIV care services: 1. HIV primary care, including antiretroviral (ARV) treatment; 2. Retention interventions; 3. Re-engagement interventions; 4. Adherence interventions; 5. STD screening and treatment; 6. Partner services; 7. Behavioral risk reduction interventions; 8. Screening patients for behavioral health and social services' needs; 9. Linkage to behavioral health and social services; 10. Navigators to assist linking to care and accessing behavioral health and social services; 11. Navigators to assist enrollment in a health plan.

CDC HIV program grantees will collect, enter or upload, and report agency-identifying information, budget data, information on the HIV prevention and care services, and client demographic characteristics with an estimate of 2,466 burden hours. It is estimated that the 37 respondents will see approximately 200 patients per year. The respondents will take about 20 minutes to enter the data for each of the 200 patients using the monitoring and evaluation form.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden Hours
Health jurisdictions	Health Department Collaborative	37	200	20/60	2,466

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Office of Scientific Integrity  
Office of the Associate Director for Science  
Office of the Director  
Centers for Disease Control and Prevention

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